

# **Chapter 3**

## **Allocation General**

# Change record

Date	Author	Version	Change reference
16-10-2019	S. Vogelaar	3.3	Textual change
02-01-2018	J.D. de Boer	3.2	Update Donors outside the Eurotransplant area
11-08-2016	J.D. de Boer	3.1	Clarification back up procedure for intended liver split
03-11-2016	S.Y. Marks	3.0	Correction exclusion criteria extended allocation
17-10-2016	S.Y. Marks	2.9	Update exclusion criteria extended allocation
17-06-2015	S.Y. Marks	2.8	Match Comment
18-08-2014	S.Y. Marks	2.7	Update rescue information
22-04-2014	S.Y. Marks	2.6	Update EA
25-03-2014	S.Y. Marks	2.5	Update EA
29-11-2013	R. Taalman	2.4	Description Recipient oriented extended allocation added
02-07-2013	A. Verweij	2.1	Hungary included in 3.1
08-03-2013	S.Y. Marks	2.0	Textual Adjustments
13-09-2012	C.M. Tieken	2.0	Text added page 2
12-07-2012	R. Taalman	2.1	Change rescue Liver; Motivation for acceptance of rescue offer;
25-10-2011	R. Taalman	2.2	Introduction of <a href="http://www.donordata.eu">www.donordata.eu</a>
24.02.2011	R.Taalman	2.3	Major revision

The Eurotransplant Manual contains the rules and regulations for the implementation and specification of national legislation and national guidelines for waiting list management, organ procurement and allocation. It has been prepared with the best of knowledge and the utmost care. In case of discrepancies between the content of this manual and national binding provisions, the following applies:

- Insofar, as provisions about the acceptance of organ recipients to the waiting list are concerned, this manual has only an informative character. Only the national provisions which are applicable for the transplant centers are relevant and legally binding.
- For the allocation of organs only the national provisions are legally binding. The display of the allocation provisions in this Manual are based on these legally binding national provisions. As far as necessary, they have been specified by Eurotransplant in this Manual. Deviations from such specifying Eurotransplant provisions cannot be considered as a breach of the national provisions as long as the latter are not violated. Eurotransplant cannot be held liable for a potentially wrongful description in this Manual of procedures, in connection with the organ allocation, as long as the actual allocation follows national provisions.

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### **3.1 Introduction**

Eurotransplant is involved in the allocation of donor organs within Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia. This chapter will describe the general process of allocation within Eurotransplant. The more specific matching procedures used for organ allocation are described in the various organ-specific chapters of the ET manual.

The allocation procedure starts with the reporting of a donor to the Eurotransplant duty office. This procedure ends with the transplantation of the allocated organ(s) or with the termination of the allocation procedure (e.g. in case a specific organ has not been accepted). In this process, several steps can be distinguished which will be discussed in this chapter.

## 3.2 Allocation procedure

### 3.2.1 Donor reporting

Almost all donors from the centers within Eurotransplant are reported electronically. Donors from outside Eurotransplant area are always reported by fax to the Eurotransplant office.

If donors are reported electronically, this donor information is directly entered into the allocation program ENIS. In this case the allocation can be started immediately. Donors reported by fax have to be manually entered into ENIS by a duty officer. In Chapter 9 of the Eurotransplant (ET) Manual, all information regarding the donor is further explained.

### 3.2.2 Matching

Mandatory donor data to start a matching procedure are the following:

- Donor center / region
- Blood group
- Rhesus factor
- Date of birth
- Sex
- Weight
- Height
- Identity
- Cause of death
- Cadaver type (donation after cardiocirculatory death / donation after brain death)
- (Brain) Death date
- Country of citizenship
- Donor hospital
- Contact telephone number

The following data will influence the outcome of the ranking of the recipients on match lists. Therefore it is very important to report these data as soon as possible:

- Virology (HIV, HBV, HCV)
- Past history (drug abuse, malignancies)
- Presence of sepsis / meningitis
- Marginal liver donor parameters (Note: only applicable for liver match):
  - Age > 65 years
  - ICU stay with ventilation >7 days
  - BMI > 30
  - Steatotic liver >40%
  - Sodium >165 mmol/l
  - SGPT > 105 U/l
  - SGOT >90 U/l
  - Bilirubin >3 mg/dl
- HLA (only mandatory for Kidney match)

When these data are entered, a ET number is generated and the organ specific matches can be generated. The matching procedures are described in:

1. Chapter 4 (kidney),
2. Chapter 5 (liver),
3. Chapter 6 (thoracic organs),
4. Chapter 7 (pancreas),
5. Chapter 8 (intestine).

### 3.2.3 Offering

The matching procedures generate the so-called match lists per organ. On these lists all recipients selected for the match are shown in the sequence in which the organ offers must take place, according to the matching rules developed by the organ advisory committees. The different organs of a donor will be offered in the following order:

Heart+lung/heart → lung → liver → intestine → pancreas → kidney

This order also depicts which organs are leading relative to the other organs, whenever a combined organ transplant is necessary for one recipient. Prior to the first offers, the lists are screened by the duty officers on available combinations and allocation comments (see 3.2.3.1 for more information) entered by the transplant centers. After the screening, the first offers are made. In the case a recipient is registered on the waiting list for more than one organ and has different organ profiles per organ, the profile of a leading organ will be used.

Offers are made in a recipient-oriented fashion according to the above mentioned match list, i.e. the offer is for a specific recipient on the match list. If the offer is rejected for this recipient, the duty office will go on to the next recipient on the match list. All decisions of the centers are entered in the ENIS system and noted on the match list.

Eurotransplant allocates according to the following policy 'an offer is an offer'. An offer cannot be withdrawn once it is made regardless whether the donor information changes. The center to which the organ is offered should be informed about the changes. However Eurotransplant reserves the right to withdraw an offer if the allocation violates the other rules laid down in the manual.

#### 3.2.3.1 Comments for allocation

##### 3.2.3.1.1 Allocation comment

The allocation comment contains information that is relevant during the allocation process. For example: make back-up offer, participating in CCA study, XM required (all organs). These comments can only be entered by the ET Helpdesk and therefore a written request is required.

##### 3.2.3.1.2 Waiting list comment

The waiting list comment is available for the centers to help during the acceptance process of an organ. The waiting list comment can be entered in the recipient – general screen in ENIS. These notes will be visible in the recipient reports in Donordata.

##### 3.2.3.2 Primary offer

The recipient receiving the primary offer has the first right to accept the organ. The center may accept the offer and transplant the organ in the recipient that the organ was offered for. For logistic reasons Eurotransplant urges centers to give their decision of non renal organs within 30 minutes. For renal organs, the center is urged to decide within 60 minutes.

### 3.2.3.3 Secondary (reserve) offer

When the primary offer is made, the second recipient on the match list will generally receive a so-called backup or secondary offer. This offer is made to save time in the allocation procedure. For a secondary offer, the centers are also urged to decide within also a time limit of 30 minutes for non-renal organs and 60 minutes for renal organs is counted. The prime goal for a reserve offer is to gain time in the allocation process.

### 3.2.3.4 Deviation from the normal allocation scheme

When an organ is not accepted via regular allocation, Eurotransplant is allowed to deviate from the normal allocation scheme in order to prevent the loss of the organ for transplantation.

There are several reasons why an organ might not be accepted via regular allocation and a deviation is justified. Most common reasons are:

- Medical reasons: when a non-renal organ is rejected in three different centers for medical reasons (renal organ: in five different centers). In case of the liver a rescue is only initiated due to logistical reasons
- Logistical reasons: when it is not possible to reach the donor center in time, for example bad weather conditions or when the donor is unstable

Eurotransplant uses, as discussed with the national authorities, the following two types of deviated allocation:

1. Recipient oriented Extended Allocation
2. Competitive rescue allocation (Competitive center offer).

In general, Eurotransplant starts with Recipient oriented Extended Allocation. In case this is unsuccessful, Eurotransplant switches to competitive rescue allocation. In rare cases with great risk of direct loss of the organ, Eurotransplant will apply the competitive rescue allocation immediately.

**Please note:** for the liver an alteration in above mentioned allocation procedure was made.

A liver deviated allocation procedure is only initiated in case a liver has not been allocated 1 hour (Germany) or 2 hours (other countries) before the planned explantation time. Medical declines are not taken into account in the initiation of the liver deviated allocation process.

### 3.2.3.5 Remarks

#### 3.2.3.5.1 Liver allocation in case the liver is not splittable

If, ultimately, the whole liver cannot be split, the patient initially selected by the ELAS whole liver match (recipient that initially accepted the liver for split) receives the whole liver graft. The accepting center of the second split will be informed that the splitting procedure will not be performed and the offer to their recipient is therefore withdrawn.

If the initial recipient is not eligible for a whole liver graft, e.g. due to a size mismatch, the HU recipients that newly received the HU status during this allocation procedure will receive the offer of the whole liver, if applicable.

In case the liver is not accepted for the above mentioned HU recipient, the liver will be offered to the back-up recipient and other recipients according to standard protocols.

### 3.2.3.5.2 Recipient oriented extended allocation

From December 9, 2013, an adapted procedure for ‘rescue’ allocation of donor organs will be effective. This recipient oriented Extended Allocation (REAL) is implemented for the following reasons:

- Increase transparency of the rescue allocation procedure;
- Selection of suitable recipients based on donor- and recipient characteristics;
- Central allocation of the donor organ by Eurotransplant according to standard allocation criteria among the suitable recipients;
- Speeding up the rescue allocation procedure by contacting all centers in parallel;
- Improving transparency and accountability by electronically collecting the recipient selection by the transplant centers;
- Close monitoring of the rescue allocation procedure as one part of possible on-site visits of the transplant centers.

If standard allocation is not successful, Transplant centers in the region/country, where the donor organ is at that moment (to achieve short ischemic time) are contacted by telephone.

For each center, the recipients – including their original ranking on the (unfiltered) match, are presented in an online application.

From this match list, centers select up to two recipients for transplantation. The recipient choice must be entered into the application within 30 minutes after the offer. Centers can also decline the offer and register the reason for decline in this online application.

Eurotransplant offers the organ to the highest ranked recipient.

A group of recipients are excluded from the recipient oriented Extended Allocation. Reasons for exclusion are:

- Recipients registered for combined organs (not kidney);
- Recipients whom need any organ combined with a kidney and there is no kidney available; with exception of the liver due to “Kidney after Liver” rule;
- Recipients of whom the ENIS profile indicates “Extended Allocation No”;
- Recipients for whom the organ offer has been declined in the regular allocation;
- Recipient with an Accepted or Confirmed status in ENIS
- Recipients from centers who have entered in ENIS that they have no capacity for transplantation;
- Recipients whom already have the accepted status in ENIS at the time the REAL is started up;
- Recipients with a positive cross-match;
- Immunize recipients of whom the cross-match result is not available in ENIS, with exception of:
  - Liver only and Liver-kidney recipients with a PRA>5%
  - Immunized recipients with non-cytotoxic antigens.

Organ specific rules are described in the separate organ chapters.

### 3.2.3.5.3 Competitive rescue allocation

A competitive rescue offer is usually initiated when the recipient oriented extended allocation was unsuccessful or in case there is very limited time for allocation (due to unstable donor, long CIP etc.). Competitive offer is made to at least 3 centers in the region or country. The organ is then sent to the center that accepts the offer first. At

the time of acceptance of the offer the ET number of the selected recipient has to be given to the ET allocation desk. When initiating the competitive rescue the centers that have already seen the donor information, receive the offer last. The center may choose the recipient from all ABO-compatible recipients in the center.

#### 3.2.3.6 Offering the organ(s) outside the Eurotransplant area

When no suitable recipient can be found within the Eurotransplant area even after rescue allocation, the duty officer will contact the donor coordinator whether the organ should be offered outside the Eurotransplant area. If the coordinator gives consent, the offer is made to several organ exchange organizations in Europe at the same time. The organization accepting the offer first, may transplant the organ.

#### 3.2.3.7 Donors outside the Eurotransplant area

When a donor from outside the Eurotransplant area is reported, the organ will be offered via competitive rescue allocation since the organ is often reported to several organ exchange organizations at the same time. The characteristics of the offered organ(s) will be entered in the ENIS system and a match will be generated. According to the matchlist a competitive rescue offer will be done to the first eight (different) centers.

#### 3.2.3.8 Access to Donor information

Upon receiving the organ offer, the center is entitled to see the donor information. All donor and organ information (if available) can be viewed via the internet on [www.donordata.eu](http://www.donordata.eu). This is the easiest and fastest way to view both donor and recipient data at once. To view the donor data, an account for the donor data web site and the ET donor number is necessary

As of July 1, 2011 exchange of donor information via the web-based application 'donordata.eu' (or similar web-based applications in use within the ET member countries) is **mandatory**.

In exceptional cases, donor information is allowed to be provided in other ways (e.g. by fax). Exceptional cases will only be considered as such if they are included in the 'donordata.eu exceptional case description'. A description of exceptional cases will be established prior to implementation of ROPC03.10 (e.g. technical calamities)

The centers outside the ET area have no access to the Donor data website. All information is faxed.

### 3.2.4 Accepting

Upon acceptance of the organ, the transplant center will be put in contact with the donor center to make further arrangements. If necessary, the Eurotransplant duty office can assist in arranging transport.

Centers that have the secondary offer at the moment of acceptance of the primary offer will be notified that the organ offer is withdrawn.

When the organ is accepted, the recipient will receive the code "accepted" in the ENIS system and will from then on not be selected in further matching procedures.

### 3.2.5 Transport

Organizing transport is generally the responsibility of donor coordinator and transplant center. Eurotransplant can assist in establishing contact between donor and transplant coordinators, selecting flights, etc. This is mainly done in case of acceptance of kidneys. For further information concerning this subject, see chapter 9.

### 3.2.6 Organ not transplantable at time of arrival in transplant center

When an organ is deemed not transplantable (for the selected recipient) upon arrival in the transplant center, the Eurotransplant duty office must be informed immediately! Eurotransplant has to withdraw the acceptance code so the recipient will be selected in future matches again.

Furthermore, following actions must be discussed with Eurotransplant. The organ may never be discarded without consent of the Eurotransplant duty office.

### 3.2.7 Confirming

Several hours after explantation, the Eurotransplant duty office will check if the transplant center registered the transplantation in the ENIS system. If this is not done, the duty officers will try to confirm the transplantation. The transplant center is called whether the organ is (being) transplanted. If this is confirmed by the center, the recipient will temporarily receive the status “Confirmed” in our system. This status is replaced by the status “Transplanted” after the transplantation is registered. Confirming is especially important for the thoracic matches, because the HU and total country balance will immediately be adjusted. It is equally important for the liver match, where an obligation to the donor center will be generated or closed immediately upon confirmation of liver transplantation. An obligation is generated, if a liver from a donor outside the transplant centers country is transplanted into a patient in urgency HU or ACO. The receiving country then has the obligation to offer the next available liver in the same blood group to the country they receive a liver from for their HU or ACO patient.

### 3.2.8 Transplantation Registration

When the organ is transplanted, the organ can no longer be allocated and therefore the allocation procedure is closed. The transplant center must register the transplantation as soon as possible. After registration of the transplantation, the new status of the recipient will be “FU” (follow –up).

#### 3.2.8.1 Documentation of transplantation via rescue allocation

When an organ is accepted by a transplant center via rescue allocation, the transplant center must enter the following items into ENIS upon transplant registration:

1. Reason for selecting the specific recipient for transplantation
2. Person in charge for selecting the recipient

These data fields are mandatory items in the transplant registration screen.

## 3.3 Eurotransplant Duty Office

### 3.3.1 Personnel

The Eurotransplant duty office is operational 24 hours a day, 7 days per week. Personnel at the duty desk have been specially trained and are continuously being trained. After passing the allocation exam, a yearly knowledge test on the different allocation rules has to be taken by all duty officers.

#### 3.3.1.1 Tasks

All duty desk personnel is trained to work independently and is involved in all donor procedures that include:

1. Receiving and processing relevant donor data;
2. Initiating of matching procedures;
3. Offering organs to transplant centers;
4. Receiving transplant centers' decision regarding the organ offers;
5. Communicating with donor coordinator on results from allocation;
6. Assisting in contacting all organizations involved in donor procedures;
7. Organizing transports;
8. Receiving and processing requests for high urgency.

### 3.3.2 Medical Staff

#### 3.3.2.1 Supervision of duty office

The Eurotransplant medical staff is on duty 24 hours, 7 day a week as officers on call supervising allocation procedures. They also assist in all questions related to suitability of donors for organ allocation.

The medical doctor on duty is responsible if standard criteria for all allocation procedures are fulfilled. The final responsibility belongs with the medical director.

#### 3.3.2.2 Requests for high urgency

The medical doctor on duty will judge all received requests for high urgency using pre-defined criteria as mentioned in the organ-specific chapters of the ET manual. They also assist in all questions related to suitability of the recipient for high urgency request.